

REMARKS

Claims 1-4, 7, 8, 11-20 and 52 -55 are currently pending in this application. Claims 54 and 55 have been cancelled, and claim 1 has been amended herein to more particularly point out and distinctly claim the invention. No new matter has been added by way of this amendment, and support can be found throughout the specification, *e.g.*, at page 10, lines 25-27; page 12, line 24, page 14, lines 8-16 and original claim 13. Claim 1 has also been amended to delete the recitation that the polymer is sodium acrylate, and this recitation has been incorporated into new dependent claim 56.

After entry of this amendment, claims 1-4, 7, 8, 11-20 and 52, 53 and 56 will be pending in this application. Applicants respectfully request reconsideration of pending claims 1-4, 7, 8, 11-20 and 52, 53 and 56.

I. Telephonic Interviews

Applicants are grateful to the Examiner for taking the time to discuss the pending claims and prior art in the Telephonic Interviews of October 5, 2006 and October 10, 2006..

Based on those discussions and suggestions made by the Examiner, Applicants have amended claim 1 to more particularly point out and distinctly claim the invention. As suggested by the Examiner, Applicants have amended claim 1 to recite that the polymer is an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20%. Also as suggested by the Examiner, Applicants have amended claim 1 herein to delete the recitation that the polymer is a "high water absorbing" polymer and instead recite that that polymer can increase its weight by at least about 20 times its original dry weight upon contacting water, as provided in the specification, *e.g.*, at page 10, lines 25-27. Applicants thank the Examiner for these suggestions and respectfully submit that these claims are now in conditions for immediate allowance.

I. Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 55 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement (Office Action, pages 2-3). Applicants have cancelled claim 55 herein thus rendering this rejection moot.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-4, 7-8, 11-20 and 52-55 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite (Office Action, pages 3-4).

Applicants respectfully traverse this ground of rejection.

First, the Examiner opines that the term “high” in claim 1 is a relative term which renders the claim indefinite.

Applicants note that the term “high” recited in the claims is used in the context of the phrase “high water absorbing polymer,” which is explicitly defined in the specification at page 10, lines 25-27. Thus, Applicants respectfully submit that the term “high,” taken in context of the phrase “high water absorbing polymer,” is definite.

However, *solely* in an effort to advance prosecution of this application, Applicants have amended claim 1 herein to delete the recitation that the polymer is a “high water absorbing” polymer and instead recite that that polymer “can increase its weight by at least about 20 times its original dry weight upon contacting water,” as provided in the specification at page 10, lines 25-27 (a definition of term “high water absorbing” polymer). As such, Applicants submit that this amendment does not narrow the scope of claim 1.

Second, the Examiner opines that because claim 1 recites acrylate polymers, as well as sodium acrylate polymers, the claim is indefinite.

While the Applicants disagree with the Examiner’s assertion, and *solely* in an effort to advance prosecution of this application, Applicants have amended claim 1 to delete the

recitation that the polymer is sodium acrylate. New dependent claim 56 has been added, which recites the composition of claim 1, wherein the polymer is a sodium acrylate polymer or copolymer thereof.

Thus, Applicants respectfully submit that each of the pending claims complies with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of these grounds of rejection is respectfully requested.

III. Rejection Under 35 U.S.C. § 102(b)

Claims 1-4, 7, 8, 11-20, 52 and 54-55 have been rejected under 35 U.S.C. § 102 as allegedly being anticipated by Boschetti *et al.* (U.S. Patent No. 5,635,215) ("Boschetti") (Office Action, page 4).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti "teaches the spherical particles herein and suspension composition comprising the same used for injection" (Office Action page 4).

As the Examiner appreciates, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

Boschetti does not disclose each and every element recited in independent claim 1. Nowhere does Boschetti disclose swellable microspheres, *much less* a swellable microsphere comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water. As such, Boschetti does not disclose each and every element recited in independent claim 1, and, as such, cannot anticipate the claimed invention.

For at least these reasons, Applicants respectfully submit that independent claim 1 is novel of Boschetti. Similarly, each of claims 2-4, 7, 8, 11-20 and 52, 53 and 56, which depend either directly or indirectly on independent claim 1, and thus incorporate all the limitations thereof, is also novel over Boschetti. According reconsideration and withdrawal of this ground of rejection is respectfully requested.

IV. Rejection Under 35 U.S.C. § 103

A. Claims 1-4, 7, 8, 11-20, 52 and 54-55

Claims 1-4, 7, 8, 11-20, 52 and 54-55 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Boschetti (U.S. Patent No. 5,635,215) (Office Action, pages 5-7).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti “teaches the spherical particles herein and suspension [*sic*] composition comprising the same used for injection” (Office Action, page 5). The Examiner also opines that “it would have been *prima facie* obvious to a person of ordinary skill in the art...to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method” (*Id.* at pages 5-6).

However, while the Examiner appears to be focusing on the size ranges disclosed in Boschetti as the basis for the obviousness rejection, the Examiner has not provided any evidence that Boschetti discloses swellable microspheres comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water, as recited in the claims.

Where applicable, the findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 USC 103 ground of rejection. *Dillon*, 919 F.2d at 693, 16 USPQ2d at 1901; *In re Mills*,

916 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990). Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings.

Manual of Patent Examination Procedure § 2144.08 (emphasis added).

While it is true that Boschetti *generally* teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization, the reference does not teach or make obvious the claimed swellable microspheres comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water. See, e.g., *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (Bd. Pat. App. & Int'l 1992) (prior art which provides only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it does not render the invention unpatentably obvious). As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or can increase its weight by at least about 20 times its original dry weight upon contacting water (*i.e.*, high water absorbing polymers).

Boschetti does not disclose any swellable microspheres, *much less* a swellable microsphere comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water, as recited in the claims. Indeed, Boschetti discloses that cationic microspheres are preferred due to the ability to improve cell adhesion (see, e.g., Col. 2, lines 11-37; Col. 3, lines 3-10; Col. 4, lines 57-60).

Further, because the cationic microspheres disclosed in Examples of Boschetti were effective for vascular embolization, one skilled in the art would have had no motivation whatsoever to use the claimed microspheres comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water for vascular embolization *much less* for tissue bulking, which is a completely unrelated field.

Thus, for at least these reasons, Applicants submit that Boschetti does not render any of 1-4, 7, 8, 11-20 and 52, 53, and 56. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

B. Claim 53

Claim 53 was also rejected as allegedly being obvious over Boschetti in view of Tahara (U.S. Patent No. 5,298,570) ("Tahara").

Applicants respectfully traverse this ground of rejection

While it is true that Boschetti *generally* teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization, the reference does not teach or make obvious the claimed swellable microspheres. *See, e.g., Ex parte Obukowicz, 27 USPQ2d 1063, 1065 (Bd. Pat. App. & Int'l 1992).* That is, nowhere does Boschetti disclose or suggest *any* swellable microspheres, *much less* swellable microspheres comprising an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water, as recited in the claims. As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or can increase its weight by at least about 20 times its original dry weight upon contacting water (*i.e.*, high water absorbing polymers).

Furthermore, contrary to the Examiner's assertions, Tahara does not supply the disclosure of Boschetti. Tahara is cited as teaching sodium acrylate / vinyl alcohol copolymers. The Examiner asserts that it therefore would have been *prima facie* obvious to a person of skill in the art to use the sodium acrylate / vinyl alcohol copolymers as the hydrophilic polymer, and the alleged motivation comes from the fact that this copolymer was known. The Examiner also cites *Ex parte Winters* 11 USPQ 2d 1387, 1388 for the proposition that "[t]he employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious" (Office Action, page 7).

However, when read in context, *Winter* actually states that "[some] compounds, CAJD-534149v1

falling within the scope of a prior art genus, are unpatentable in the absence of a showing of unexpectedly superior results" (*Winter* at 1388 (citing *In re Lemin*, 332 F.2d 838, 141 (CCPA 1964)). Here, Applicants have disclosed in the specification a number of advantages of the claimed swellable microspheres over prior art microspheres, e.g., at page 13, lines 3-16.

For at least these reasons, Applicants submit that claim 53 (as well as new claim 56) is non-obvious over Boschetti in view of Tahara. As such, Applicants respectfully request that this rejection be reconsidered and withdrawn.

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that this application is now in condition for immediate allowance. *If the Examiner disagrees, Applicants respectfully request that the Examiner call the undersigned at the number listed below.*

A Petition for a One (1) Month Extension of Time is submitted herewith, with provisions for the required fee, which extends the response period from September 18, 2006 to, and including, October 18, 2006. The Petition further authorizes the PTO to charge the one month extension fee of \$60 to Jones Day Deposit Account No. 50-3013, which reflects Applicant's Small Entity Status. A Request for Continued Examination (RCE) Transmittal is also submitted herewith, which authorizes the PTO to deduct the RCE fee of \$395.

Applicants believe no other fees are due in connection with this RCE and response. However, if there are any other fees due, please charge them to Deposit Account 50-3013. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the Petition filed concurrently herewith, such an extension is requested and the fee should

be charged to our Deposit Account. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,



Date: Oct. 18, 2006

For: Anthony M. Insogna
Tamera M. Pertmer, Ph.D. (Reg. No. 47,856)
JONES DAY
12750 High Bluff Drive, Suite 300
San Diego, CA 92130
(858) 314-1181

For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
222 East 41st Street
New York, NY 10017-6702
(212) 326-3939